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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,344	01/19/2001	Neil T. Parkin	11068-033-999	7661

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/766,344

Applicant(s)

PARKIN ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 122-150 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 122-150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/13/4, 5/19/4.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 122-150 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

The claimed method of assessment in claims 122, 126, 127, 138, 139 and 149 does not have a clear point for reasons of record.

Applicant asserts that detecting the presence of the mutations is associated with protease inhibitor resistance and the skilled artisan would be able to evaluate whether the therapy is effective. Applicant cites teachings in the specification, drawn to determining whether certain mutations affect the susceptibility of certain protease inhibitors.

Applicant's arguments have been fully considered, but are found unpersuasive. It is not argued that the specification has support for evaluation. The claims must recite steps to address the effectiveness of the protease therapy, which is recited in the preamble of the claims. In the last Office correspondence, specific discussions in the disclosure were cited in order to aid applicant to obviate this rejection. Incorporation of this language in to the claims would clarify the intent of the methods claimed.

Although applicant states that amendments to the claims obviate the discrepancy between claims 131-137 and claims 139-149, no amendment remedying this rejection can be found. Claims 131-137 still state that certain mutations result in a decrease in susceptibility to

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saquinavir and/or indinavir, while claims 139-149 still state that the same mutations indicate an increase in susceptibility to saquinavir and/or indinavir.

With respect to the lack of antecedent basis cited against claims 125, 130-134, 136, 137 and 143-145 applicant separately argues that each claim has antecedent basis and points to support in the claims from which these dependent claims ultimately depend. However, a lack of antecedent basis in claims is determined when limitations recited in a dependent claim are not found in the recited claim from which they depend, not the claim they ultimately depend from.

In response to the rejection of claim 150, applicant summarizes teachings in the specification with regard to the indicator gene and vector. Applicant asserts that the skilled artisan would readily recognize the metes and bounds of claim 150 because the relationship between the indicator and the activity of the HIV protease would be readily apparent.

Applicant arguments have been fully considered, but are found unpersuasive. Claim 150 is drawn to a vector comprising an HIV protease with certain mutations and an indicator gene. The claim states that the quantity of expression of the indicator gene depends on the activity of the HIV protease encoded by the vector. Since the vector would express the protease, it would also express the indicator gene. The amount of expression of either product is not separately designated in the vector or the claim. It remains unclear what would affect the expression of the protease and how this affected expression would change the amount of expression of the indicator. Therefore, it remains unclear what the indicator gene is indicating.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 122-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Craig et al. (AIDS. 1998; 12: 1611-1618) for reasons of record.

Applicant states that the claims have been amended to obviate the rejection. Applicant also argues that none of the HIV strains discussed by Craig et al. comprise the specific combination of mutations recited by the instant claims.

A review of the amended claims and the teachings of Craig et al. have been reviewed, but are found unpersuasive. Claims 122-126 still recite codons 90, 54, 46 and 93 that Craig et al. teach result in a reduced sensitivity to saquinavir, indinavir, ritonavir, amprenavir and nelfinavir, see Table 2 on page 1615. Therefore, the teachings of Craig et al. still anticipate claims 122-126 for reasons of record.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shanon Foley  
Primary Examiner  
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